REMARKS

Appreciation is hereby expressed to Examiner Ceperley for the interview so courteously granted on May 22, 2001. Pursuant to that interview, Claims 7 and 8 have been canceled and Claims 1-4 and 11 amended to more definitely set forth the invention and obviate the rejections. In addition, new Claims 12-16 are hereby presented. Claims 12-15 are dependent, directly or indirectly, upon Claim 3, and new Claim 16 calls for an immunoassay method using the immunoassay reagent of Claim 3 and as described in the specification in the discussion bridging pages 11-16. The present amendment is deemed not to introduce new matter. Claims 1-6 and 8-16 are in the application.

Reconsideration is respectfully requested of the objection under 35 U.S.C. § 112, first paragraph, to the specification. During the interview, the reaction schemes and compositions of the immunoassay reagents was discussed at length, and the Examiner was presented with a chart showing the principal of measurements of Claim 3, copy attached hereto. Also, there was a discussion with respect to the differences between the reaction scheme and using the immunoassay reagents of Claim 1 and that of Claim 3. Also, there was reference to the specification which describes the reactions sequences and the immunoassay reagents. It is therefore believed that the specification is completely adequate in providing a description of the invention, and that it clearly teaches one of ordinary skill in the art how to make and/or practice the

invention. Consequently, it is respectfully submitted that the Examiner would be justified in withdrawing the rejection. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claims 1-6 and 9-11 under 35 U.S.C. § 112, first paragraph, on the ground that the claimed subject matter was not described in the specification in order to enable one skilled in the art to make or use the invention. During the interview, various proposals were made concerning adding process limitations (as tacitly suggested by the Examiner on page 3 of the Office Action), but after due consideration, it was decided that process limitations in the composition Claims 1 and 3 would add nothing to their patentability. However, after consideration of the reaction scheme, it was concluded at the interview that Claims 1 and 3 should be amended in the manner set forth herein to clarify that the components of the immunoassay reagent are not mixed before conducting an assay. The language to be employed in the amendments herein was discussed with the Examiner, and it is believed that the claims as now amended obviate the rejection. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claims 1-11 under 35 U.S.C. § 112, second paragraph, as being indefinite. The claims have been amended in accordance with the Examiner's suggestions, and it is therefore believed that the rejection is now moot. Withdrawal of the rejection is accordingly

respectfully requested.

Reconsideration is respectfully requested of the rejection of Claims 1-8 and 11 under 35 U.S.C. § 102(b) as anticipated by Kasahara, et al. (4,582,792).

As discussed at the interview, the reagents recited in Claim 1 (components (a)-(c)) are not initially mixed but are used as described in the specification on page 8, line 21 to page 9, line 24. Moreover, the reagents described in Claim 3 are maintained separate and apart until sequentially mixed. The reaction scheme for the components called for in Claim 3 are described in the specification on page 11, line 14, through page 15, line 8.

It will be seen after a review of these sections of the specification that the principals of the assays of the present invention are completely different from the assay components and processes disclosed in both Kasahara '792 and Kasahara '105.

In particular, the insoluble carrier in the present invention is different from the solid phase in Kasahara '792. In the present invention, the insoluble carrier is used not only to immobilize the antibody, enzyme and the like but also to generate aggregates resulting from the antigen-antibody reaction. The agglutination of the insoluble carrier results in an increase in turbidity of the reaction mixture which changes its light absorbance. In such an instance, the steric hindrance of resulting aggregates reduces the occurrence of the enzyme inhibitor to bind to the enzyme on the insoluble carriers that participate in the aggregation. As a

consequence, the enzyme is prevented from being deactivated and, instead, allowed to react with the substrate, thereby resulting in a change in absorbance.

In contradistinction, in the Kasahara '792 reference, the solid phase is used to merely immobilize the antibody, enzyme and the like. These fundamental differences in the immunoassay reagent and reaction scheme can be supported by reference to Kasahara '792, column 4, line 67, wherein it is pointed out that spherical beads having a diameter of 6 mm are used as a solid phase. It is apparent that such large beads as used in Kasahara '792 cannot be aggregated to effect the turbidity and result in steric hindrance of the reaction mixture as in the present invention.

Moreover, when an antigen or antibody in a sample is detected and the enzyme is immobilized on the carrier as in the present invention of Claim 1, the enzyme inhibitor is not carried on any solid substance. Further, in Claim 3, when the antibody and enzyme inhibitor are immobilized on the carrier, the enzyme is not immobilized.

In contrast, in Kasahara '792, when the antibody and enzyme are carried on different solid phases, the antigen and enzyme inhibitor should be combined to constitute the combination material. Alternatively, when the antibody and enzyme inhibitor are carried on different solid phases, the antigen and enzyme should be combined to constitute the combination material.

Moreover, in Kasahara '792, the antibody and enzyme or enzyme

inhibitor are coupled to different parts of the same polymer. Such a structure is not used in the present invention. Moreover, in the immunoassay reagent of the present invention, one of either of the enzyme or enzyme inhibitor is not carried on the insoluble substrate, but constitutes another separate component of the reagent. Further, in the case of detecting a target antigen or antibody of the present invention, the target antigen or antibody is not a component of the reagent.

Further, the reagents of the present invention in Kasahara '792 are far different and such differences are due to the differences of the principals of the assays. Particularly, the present invention utilizes the reaction between the enzyme and enzyme inhibitor which are inhibited by steric hindrance caused by agglutination of the carriers due to the antigen-antibody reaction.

In view of the foregoing, it is respectfully submitted that the Kasahara '792 reference in no way discloses the immunoassay reagents and methods of using same as called for in the claims herein as amended. Consequently, the Examiner would be justified in no longer maintaining the rejection. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claims 1-8 and 11 under 35 U.S.C. § 102(b) as anticipated by Kasahara '105.

The Kasahara '105 reference further uses a reaction of abizin and biotin in addition to the method set forth in the Kasahara '792

reference. It is therefore seen that the Kasahara '105 reference is further different from the present invention for the reasons discussed above. Consequently, the Examiner would be justified in no longer maintaining the rejection. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claims 1-11 under 35 U.S.C. § 103(a) as being unpatentable over either of Kasahara, et al. '792 or Kasahara, et al. '105 in view of Ashihara, et al. '048.

The Kasahara '792 and Kasahara '105 references are discussed above.

As for the Ashihara '048 reference, it discloses an anti-enzyme-antibody reaction and does not use an insoluble carrier as called for in the claims of the present application. Thus, the reagent disclosed in the Ashihara '048 reference is fundamentally different from that of the present invention as recited in the claims herein, as well as the principle of measurement. Further, the present invention is far different from Kasahara '792 and '105 for the reasons discussed above.

In view of these fundamental differences, it is respectfully submitted that combining the references in the manner suggested by the Examiner would not result in the immunoassay reagent or method of using same as now called for in the claims herein. Consequently, the Examiner would be justified in no longer maintaining this rejection. Withdrawal of the rejection is

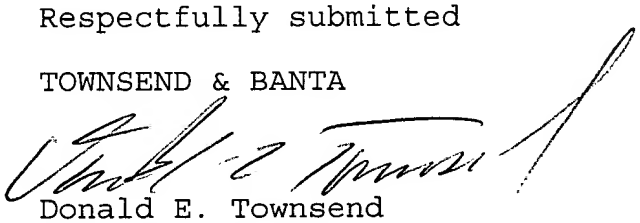
accordingly respectfully requested.

The prior art of record is noted, the Examiner apparently recognizing that the cited references are not relevant inasmuch as the Examiner has not predicated a rejection thereon.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance and early action and allowance thereof is accordingly respectfully requested. If there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems.

Respectfully submitted

TOWNSEND & BANTA



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MARKED UP VERSION OF AMENDED CLAIMS 1, 2, 3, 4, 5 AND 11

1. (Twice Amended) An immunoassay reagent for use in [the] a quantitative determination of a target antigen or antibody present in a sample, said reagent [containing] comprising the following components:

(a) An insoluble carrier which carries an enzyme and an antibody or antigen [corresponding to] reactive with said target antigen or antibody, said insoluble carrier comprising at least one selected from the group consisting of an organic polymer powder article, microorganism, blood cell and cell membrane fragment;

(b) an enzyme inhibitor for inhibiting [the] activity of said enzyme; and

(c) a substrate with which the enzyme reacts[.], said components (a)-(c) being maintained separate and apart and mixed together only with a sample containing the target antigen or antibody.

2. (Amended) The immunoassay reagent as recited in claim 1, [characterized as comprising] wherein a first reagent [which] contains said insoluble carrier in (a) above, and a second reagent [which] contains said enzyme inhibitor and said substrate in (b) and (c) above.

3. (Twice Amended) An immunoassay reagent for use in [the] a quantitative determination of a target antigen or antibody present in a sample, said reagent [containing] comprising the following components:

(a) an insoluble carrier which carries an enzyme inhibitor and an antibody or antigen [corresponding to] reactive with said target antigen or antibody, said insoluble carrier comprising at least one selected from the group consisting of an organic polymer powder particle, microorganism, blood cell and cell membrane fragment;

(b) an enzyme whose activity is inhibited by said enzyme inhibitor; and

(c) a substrate with which the enzyme reacts[.], said components (a)-(c) being maintained separate and apart and sequentially mixed together only with a sample of target antigen or antibody.

4. (Amended) The immunoassay reagent as recited in Claim 3, [characterized as comprising] wherein a first reagent [containing] contains said insoluble carrier, a second reagent [containing] contains said enzyme, and a third reagent [containing] contains said substrate.

11. (Twice Amended) An immunoassay method for quantitatively determining a target antigen or antibody present in a sample, comprising:

mixing the immunoassay reagent of claim 1 with the sample to thereby [cause] facilitate an enzyme reaction and an antigen-antibody reaction resulting in [the form of an] agglutination [reaction] of the insoluble carrier; and

measuring the [degrees of the reactions occurred]

absorbance of resulting mixture as an index of an amount of target antigen or antibody in the sample.